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| EXAMINER |
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CALAMITA, HEATHER

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| ART UNIT | PAPER NUMBER |
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1637

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/886,055

Applicant(s)

STRYER ET AL.

Examiner

Heather G. Calamita, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 12-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 1-11 and SEQ ID NOs 55 and 56 filed on March 16, 2004, is acknowledged. Applicant's arguments filed 03/16/2004 have been fully considered but they are not persuasive. Traversal was on the grounds the methods corresponding to Groups I, II, V, VI VIII and X are related methods for identifying or representing the sensory perception of specific compounds. The examiner maintains that the search and examination of the groups together would be burdensome for the reasons stated in the office action mailed on September 30, 2003. Further with regard to Applicants' argument regarding the sequence election, while the sequences may be organized into a collection or a library they are still patentably distinct sequences. These amino acid sequences are unrelated because the proteins encoded by these sequences differ in structure, function and in biological activity. Finally with regard to the nucleic acid sequences, Applicants did not submit evidence showing the species to be obvious variants, nor did Applicants' clearly indicate on the record this to be the case. The examiner, therefore, maintains the restriction requirement made previously, as each group is correctly separated as unrelated or patentably distinct and the restriction is **herein made final**. Claims 11-22 are withdrawn from further consideration by the examiner, 37 CFR 1.14(b), as being drawn to a non-elected invention. Pending claims to be examined are claims 1-11 and SEQ ID NOs 55-56.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject

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matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krautwurst et al. (Cell, 1998) in view of Burford et al. (US 2004/0224314).

Krautwurst teaches the method steps of claim 1.

(a) providing a representative class of n olfactory receptors or ligand-binding domains thereof (see p. 918 col. 2 paragraph 4);

(b) measuring values X_1 to X_n representative of at least one activity of the one or more odorants selected from the group consisting of binding of the one or more odorants to the ligand-binding domain of at least one of the n olfactory receptors, activating at least one of the n olfactory receptors with the one or more odorants, and blocking at least one of the n olfactory receptors with the one or more odorants (see p. 919 col. 1 and col. 2 lines 1-11); and

(c) generating a representation of sensory perception from the values X_1 to X_n ; wherein at least one of the n olfactory receptors has an amino acid sequence of SEQ ID NO: 56 (see p. 919 col. 2 last paragraph, p. 920 col. 1 and col. 2 and Figure 3).

With regard to claim 2, Krautwurst et al. teach at least one of the olfactory receptors specifically recognizes the odorant, and there are between 5 and 350 of the n olfactory receptors selected from the listed amino acid sequences (see Figure 3 and abstract). Pooled chimeric receptors are screened with 26 different odorants. With regard to claim 3, Krautwurst et al. teach at least two different activities are measured to provide the values X_1 to X_n (see Figure 3 and legend). The response to 26 different odorants (presence and absence) is measured. With regard to claim 4, Krautwurst et al. teach each odorant receptor is expressed in cells, and the cells expressing each odorant receptor are located at an identifiable position (see p. 918 col. 2 last paragraph, p. 920 panel A Figure 2 legend). With regard to claim 5, Krautwurst et al. teach at least one olfactory receptor is soluble, and binding of odorant to a ligand-binding domain of

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the soluble olfactory receptor is measured in solution (see p. 918 col. 1 paragraph 2). The receptors are soluble in the cell before they are translocated to the plasma membrane. With regard to claim 6, Krautwurst et al. teach at least one olfactory receptor is in solid state, and binding of odorant to a ligand-binding domain of the solid-state olfactory receptor is measured on a substrate (see p. 919 col. 1 first full paragraph lines 7-9, p. 920 col. 2 paragraph 2, p. 921 col. 1 lines 7-9 and Figure 4 legend). With regard to claim 7, Krautwurst et al. teach the value measured for binding is above a preset limit for specific binding to olfactory receptors (see Figure 4 and legend). The baseline calcium level is compared to the calcium levels after binding. With regard to claims 8 and 9, Krautwurst et al. teach the value measured for activating an olfactory receptor is derived from a signal selected from the group consisting of intracellular Ca^{2+} , CAMP and IP_3 (see p. 918 col. 2 paragraph 3 lines 1-19). With regard to claim 10, Krautwurst et al. teach the value measured for blocking an olfactory receptor is at least a reduction in binding of the odorant or activation by the odorant (see p. 919 col. 2 paragraph 2 lines 12-16). Desensitization is a reduction in activation of the signaling system when the odorant binds. With regard to claim 11, Krautwurst et al. teach the sensory perception is generated with a neural network (see the abstract). HEK-293 cells are transfected with chimeric receptors found on neurons, therefore this meets the claim limitation.

Krautwurst et al. do not teach SEQ ID NOs 55 and 56.

Burford et al. teach SEQ ID NOs 55 and 56 (see SEQ ID NOs 27 and 66 respectively as well as the attached alignments).

It would have been prima facie obvious to utilize the method as taught by Krautwurst et al. (Cell, 1998) with the sequences as taught by Burford et al. (US 2004/0224314) since Burford et al. note "The largest subfamily of GPCRs, the olfactory receptors, are also members of the rhodopsin-like GPCR family. These receptors function by transducing odorant signals. Numerous distinct olfactory receptors are required to distinguish different odors. Each olfactory sensory neuron expresses only one type of

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olfactory receptor, and distinct spatial zones of neurons expressing distinct receptors are found in nasal passages. However, the expression of olfactory-like receptors is not confined to olfactory tissues.

(see p. 2 paragraph 0008).” An ordinary practitioner would have been motivated to use the method as taught by Krautwurst et al. (Cell, 1998) with the sequences as taught by Burford et al. (US 2004/0224314) in order to assess the physiological functions of these receptors in the presence of a variety of odorants.

Summary

4. No claims were allowed.

Correspondence

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 5:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at 571.272.0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number 571.273.8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571.272.0547.


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hgc


JEFFREY FREDMAN
PRIMARY EXAMINER
4/12/05